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Please find attached courtesy copy of the Declaration Pursuant to 37 CFR 1.132 and the Curriculum Vitae.

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DOCKET NO. STAN-190

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Defu Zeng et al.	Confirmation No. 3043
Serial No.	:	09/844,544	Art Unit: 1644
Filed	:	April 27, 2001	Examiner: Marianne DiBrino
For	:	METHODS FOR INHIBITION OF POLYCLONAL B CELL ACTIVATION AND IMMUNOGLOBULIN CLASS SWITCHING TO PATHOGENIC AUTOANTIBODIES BY BLOCKING CD1-MEDIATED INTERACTIONS	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 CFR §1.132

Sir/Madam:

I, Dr. Samuel Strober, M.D., do hereby declare as follows:

1. I am a Professor of Medicine in the Department of Medicine, Division of Immunology, Stanford University School of Medicine, Stanford, CA. I received my M.D. from Harvard Medical School, Boston, Magna Cum Laude in 1966. I have over thirty years of experience in immunology. My Curriculum Vitae is attached as Appendix A.

2. I am familiar with the prosecution history of the above-identified patent application and the pending obviousness issues.

3. I am submitting this declaration to show that the use of anti-CD1 antibody to treat lupus is not obvious over the prior art cited by the Examiner. The references used by the Examiner include Zeng et al., Subsets of transgenic T cells that recognize CD1 induce or prevent murine lupus: Role of cytokines. J. Exp. Med., 187:525-536, 1998 and Amano et al., CD1 expression defines subsets of follicular and marginal zone B cells in the spleen: β_2m-dependent and independent forms. J. Immunol., 161:1710-1717, 1998. The Examiner indicates that the results of the Zeng et al. publication in combination with the Amano et al. publication makes obvious the invention of the use

of anti-CD1 mAb to treat lupus. Both these publications are the result of experiments conducted in my laboratory at Stanford University.

4. It is well known in the art that a subset of T cells, CD4 helper T cells, interact with MHC Class II molecules on B cells and thereby augment the production of IgM and IgG antibodies. See Swain S.L., Immunol. Rev., 74:129, 1983 and Swain et al., J. Immunol. 132:1118-23, 1984. CD4 T cells that are not CD1 reactive T cells account for 95-96% of all CD4 T cells in NZB/W mice and other well studied mouse strains. See Zeng et al., J. Clin. Inv. 112:1211-1222, 2003. CD1 reactive T cells, which interact with the MHC-related molecule, CD1, on B-cells account for about 4-5% of CD4 T cells in these mice strains, whereas in the transgenic mice, i.e., the mice used in the experiments of the Zeng et al J. Exp. Med., 187:525-536, 1998 publication, 100% of CD4 T cells are CD1 reactive because of the introduced transgene. See Zeng et al., J. Clin. Inv. 112:1211-1222, 2003 and Zeng et al., J. Exp. Med., 187:525-536, 1998.

5. It is widely believed that CD4 helper T cells are responsible for augmenting the production of pathogenic autoantibodies in lupus. In fact, the landmark paper of Wofsy and Seaman teaches that CD4 helper T cells reactive with MHC Class II molecules, rather than the CD1 reactive T cells, interact with B cells to facilitate the production of pathogenic autoantibodies in lupus prone NZB/W mice. See Wofsy and Seaman, Successful treatment of autoimmunity in NZB/NZW F1 mice with monoclonal antibody to L3T4, J. Exp. Med., 161(2):378-91, 1985. This teaching is based on the amelioration of lupus by administration of anti-CD4 mAb that depletes CD4 helper T cells. This report is widely interpreted in the lupus field as showing that the 95-96% of CD4 T cells that interact with MHC class II and that do not interact with CD1 are required for the production of pathogenic autoantibodies; and that the 3 to 4% of $CD4^+$ T cells that interact with CD1 are expected to make a minor contribution to autoantibody production. Thus, there was no reason to believe by those versed in the field that the administration of anti-CD1 mAb, that blocked the contribution of a minority of CD1 reactive T cells, would affect autoantibody production and ameliorate lupus. This is because the vast majority of CD4 T cells (non-CD1 reactive T cells) would still be capable of interacting with B cells via MHC Class II molecules to mediate the disease. Overall, as shown in the present patent application, the unexpected result of the anti-CD1 treatment of NZB/W mice is that

the small minority of CD1 reactive T cells in the NZB/W mice are responsible for helping B cells to produce the majority of the pathogenic autoantibody production.

6. In conclusion, the Amano et al. and Zeng et al. publications do not teach about the contribution of CD1 reactive versus MHC Class II reactive CD4 T cells to lupus, because in the transgenic mouse studies described by the cited art, an unnatural 100% of the CD4 T cells are CD1 reactive, and none are MHC Class II reactive T cells.

7. Zeng et al. and Amano et al. show that there are two subsets of transgenic T cells that react with CD1, one that is Th1 biased and that induces lupus, and another that is Th2 biased and that protects against lupus. These reports do not teach about whether CD1 reactive T cells in non-transgenic mice are predominantly biased toward Th1 or Th2 cytokine patterns, and thus whether the CD1 reactive cells would induce or protect against lupus. In other autoimmune diseases, such as EAE and the autoimmune diabetes of NOD mice, activation of CD1 reactive T cells with the glycolipid, alpha galactosyl ceramide, induces a Th2 pattern and ameliorates disease. See Sharif et al., Nature Medicine, 7:1057-62, 2001 and Jahng et al., J. Exp. Med., 194:1789-99, 2001. In the NOD mice, Lehuen and her colleagues showed that deficiency of CD1 reactive T cells induced by targeted inactivation of the CD1 gene worsens disease, and an increase in the number of CD1 reactive T cells by insertion of a Vα14 transgene improves disease. See Lehuen et al., J. Exp. Med. 188:1831-39, 1998. These results teach against the pathogenic role of CD1 reactive T cells in autoimmune disease, and instead teach that they are beneficial.

8. Singh et al reported that deficiency of NK T cells in NZB/W mice by targeted inactivation on the CD1 gene worsens lupus. This teaches against a pathogenic role of NK T cells in lupus in NZB/W mice. See Singh et al., 2001, Arth. Rheum. Suppl., Vol 44, pp 283. Chan and his colleagues reported that lupus prone MRL/lpr mice that are CD1 deficient develop worse lupus skin disease than wild-type MRL/lpr mice. See Chan et al., J. Immunol., 167:2985-2990, 2001. Thus, these publications teach against a pathogenic role of CD1 reactive T cells in the lupus disease of MRL/lpr mice. Yang et al. have shown that CD1d deficiency exacerbates lupus in another model of lupus. See Yang et al., Immunoregulatory role of CD1d in the hydrocarbon oil-induced model of lupus nephritis, J Immunol., 171(4):2142-53, 2003. Yang et al. (2003) have also demonstrated an expansion of NKT cells, i.e., CD1d reactive cells, with α-GalCer and improved dermatitis in a model

used to study the pathogenesis of lupus. See Yang et al., Repeated α-galactosylceramide administration results in expansion of NK T cells and alleviates inflammatory dermatitis in MRL-lpr/lpr mice, J Immunol., 171(8):4439-46, 2003.

9. When the teaching that activation of CD1 reactive T cells ameliorate autoimmune disease such as EAE and diabetes via their Th2 bias and the teaching that deficiency of CD1 reactive T cells in lupus prone NZB/W and MRL/lpr mice worsens lupus are taken into account, a person of skill in the art would not expect that anti-CD1 mAb treatment would ameliorate lupus. They would expect the opposite.

10. Overall, the Zeng at al. and Amano et al. references do not make obvious the use of anti-CD1 antibody for the treatment of lupus.

11. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that making of willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the applications or any patent issuing thereon.

Respectfully submitted,

Dated: April 27, 2006

Samuel Strober, M.D.
Professor of Medicine
Department of Medicine
Division of Immunology
Stanford University School of Medicine
Stanford, CA

APPENDIX A
CURRICULUM VITAE

Samuel Strober, M.D.

Military Status: Three years' active duty in United States Public Health Service, Honorable Discharge, June 23, 1970

Education:

1961	A.B. Columbia College, New York City, Liberal Arts
1966	M.D. Harvard Medical School, Boston, Magna Cum Laude

Honors:

1966	Leon Resnick Memorial Research Prize, Harvard Medical School
1966	Alpha Omega Honorary Society
1971-1976	Career Development Award from NIAID
1984	Diane Goldstone Memorial Lecturer, Massey Cancer Center
1986	John Putnam Merrill Memorial Lecturer, Harvard Medical School
1987-1989	Federal Advisory Committee, Transplantation Biology and Immunology Subcommittee, NIH
1989	Ray A. and Joan B. Kroc Visiting Professor, University of Michigan
1993	E. Donnall Thomas Annual Lecture, Fred Hutchinson Cancer Research Center
1996	President, Clinical Immunology Society

Training and Experience:

1962-1963	Research Fellow, part time, Surgical Research Laboratory, Peter Bent Brigham Hospital, Boston, MA, Head: Professor J.E. Murray
1963-1964	Research Fellow, Cellular Immunology Research Unit, Oxford University, Oxford, England, Head: Professor J.L. Gowans
1965-1966	Research Fellow, Surgical Research Laboratory, Peter Bent Brigham Hospital, Boston, MA
1966-1967	Intern, Department of Medicine, Massachusetts General Hospital, Boston, MA, Professor Alexander Leaf, Head, Department of Medicine
1967-1970	Research Associate, Laboratory of Cell Biology, National Cancer Institute, NIH, Bethesda, MD, Head: Dr. L. W. Law
1970-1971	Senior Assistant Resident, Department of Medicine, Stanford University School of Medicine, Stanford, CA
1971-1972	Instructor in Medicine, Department of Medicine, Division of Immunology, Stanford University School of Medicine, Stanford, CA
1972-1978	Assistant Professor of Medicine, Department of Medicine, Division of Immunology, Stanford University School of Medicine, Stanford, CA

1976-1981	Investigator, Howard Hughes Medical Institute, Miami, FL
1978-1982	Associate Professor of Medicine, Department of Medicine, Division of Immunology, Stanford University School of Medicine, Stanford, CA
1978-1997	Chief, Division of Immunology and Rheumatology, Department of Medicine, Stanford University School of Medicine, Stanford, CA
1982-present	Professor of Medicine, Department of Medicine, Division of Immunology, Stanford University School of Medicine, Stanford, CA

Editorial Boards:

1982-1984	Associate Editor, Journal of Immunology
1982-1985	Associate Editor, Transplantation
1984-present	Associate Editor, International Journal of Immunotherapy
1992-present	Associate Editor, Transplantation Immunology
1998-2002	Member, Biology of Blood and Marrow Transplantation

Institutional Boards:

1992-2005	Member, Board of Directors, La Jolla Institute for Immunology
2005-Present	Chairman, Board of Directors, La Jolla Institute for Immunology

Societies:

1989-1997	Councilor, Clinical Immunology Society
1996	President, Clinical Immunology Society
	American Association of Immunologist
	American Society for Clinical Investigation
	American College of Rheumatology
	American Society of Transplantation Physicians
	Western Society for Clinical Investigation
	American Association of Physicians
1986-1989	Councilor, Transplantation Society

Advisory Committee:

1987-1989	NIH Transplantation Biology and Immunology Study Section

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